VIORA

JUN 10 2009

510(k) Summary:

Trios™ System

Company Name:
Viora Ltd.

Contact Person:
Danny Erez
CEO

Telephone: +972-3-5622248
Fax: +972-3-5622247
E-mail: omri@vioramed.com

Authorized US Agent:

Josef Luzon - CEO
Viora Inc.
30 Montgomery Street, Suite 660
Jersey City, NJ 07302

Telephone: (201) 332-4100
Fax: (201) 332-4200
E-mail: josef@vioramed.com

Date prepared: February 12, 2009

Trade Name:
Trios™ System

Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Common/usual name: Trios IPL System

Product Code: ONF

Regulation No.: 878.4810

Class: II

Panel identification: General and Plastic Surgery Panel.

VIORA

Predicate Device:
Radiancy Mistral Device from Radiancy (Israel) Ltd, Yavne, Israel, cleared under 510(k) # **K072331**;
IFL Professional System from Cyden Ltd, Swansea, Wales, UK, cleared under 510(k) # **K050165; McCue Energist Ultra VPL Intense Pulse Light System** from McCue PLC, Southhampton, UK, cleared under 510(k) # **K060234** and
Lumenis Family of IPL Systems from Lumenis Inc, Santa Clara, CA, USA, cleared under 510(k) # **K030527**

Description of the device:
The use of Trios™ in aesthetic applications is based on the principle of Selective Photothermolysis. According to this principle, pulsed light parameters (wavelength, pulse duration and energy fluence) are chosen to selectively target light sensitive cells while minimizing damage to surrounding tissues.

Trios™ consists of the following major components:

- Main Console
- Operator Control Panel
- Three Hand Pieces

The main console contains the high voltage electronics, the control panel, monitoring modules and the cooling system.

The hand pieces house the mechanism which generates the light pulse. The hand piece is connected to the system console by an umbilicus cord containing electrical wiring. Light from a Xenon flash lamp, located in the hand piece, is directed through a long-pass optical filter and focused into a transparent light guide that is placed in contact with the skin.

Indications for Use:
The Trios™ system is indicated for long term stable, or permanent, hair reduction; for the treatment of benign cutaneous vascular lesions and the treatment of benign pigmented lesions and for the treatment of mild to moderate inflammatory Acne Vulgaris.

VIORA

Substantial Equivalence:
The Trios™ System has the same intended use and the same performance characteristics as the following predicate devices: **Radiancy Mistral Device** from Radiancy (Israel) Ltd, Yavne, Israel, cleared under 510(k) # **K072331**; **IFL Professional System** from Cyden Ltd, Swansea, Wales, UK, cleared under 510(k) # **K050165; McCue Energist Ultra VPL Intense Pulse Light System** from McCue PLC, Southhampton, UK, cleared under 510(k) # **K060234** and **Lumenis Family of IPL Systems** from Lumenis Inc, Santa Clara, CA, USA, cleared under 510(k) # **K030527.** The Trios™ System is therefore substantially equivalent to those devices.

Conclusion -
The evaluation of the Trios™ System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2009

VIORA Limited
% Viora Incorporated
Mr. Josef Luzon
Chief Executive Officer
30 Montgomery Street, Suite 660
Jersey City, New Jersey 07302

Re: K090399
Trade/Device Name: Trois™ System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: ONF
Dated: May 31, 2009
Received: June 3, 2009

Dear Mr. Luzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

k090399

INDICATIONS FOR USE

510(k) Number (if known): k090399

Device Name: Trios™ System

Indications for Use: The Trios™ system is indicated for long term stable, or permanent, hair reduction; for the treatment of benign cutaneous vascular lesions and the treatment of benign pigmented lesions and for the treatment of mild to moderate inflammatory Acne Vulgaris.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090399